Paper No. 34

THIS OPINION WAS NOT WRITTEN FOR PUBLICATION

The opinion in support of the decision being entered today (1) was not written for publication in a law journal and (2) is not binding precedent of the Board.

UNITED STATES PATENT AND TRADEMARK OFFICE

_____

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

_____

Ex parte ARTHUR L. HORWICH,
MINGYUAN CHENG,
RICHARD MALLBERG,
DONALD S. READING
and ALAN MYERS

_____

Appeal No. 1995-2374
Application 07/673,158[1]

_____

ON BRIEF

_____

Before WINTERS, WILLIAM F. SMITH, and LORIN, Administrative Patent Judges.

WILLIAM F. SMITH, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 of the examiner's decision refusing to allow claims 5 through 9 and 11 through 18, all the claims pending in the application.

[1] Application for patent filed March 18, 1991. According to appellants, this application is a continuation of Application 07/261,573, filed October 24, 1988 (abandoned).

Claims 5, 11, and 16 are illustrative of the subject matter on appeal as read as follows:

5. A DNA segment consisting essentially of an isolated, non-chromosomal DNA segment encoding Hsp60, a mitochondrial eucaryotic protein having a molecular weight between 55,000 and 65,000 by SDS-polyacrylamide gel electrophoresis under denaturing conditions, wherein the Hsp60

(a) has at least 80% homology at the amino acid and nucleic acid level with the sequences shown in Figure 1, and

(b) interacts with newly synthesized proteins to fold them into their biologically active conformation.

11. A vector capable of autonomous replication in a cell, said vector containing an operatively linked polynucleotide sequence segment that encodes Hsp60.

16. A transformed host cell containing a vector that autonomously replicates therein, said vector containing an operatively linked polynucleotide sequence segment that encodes Hsp60.

The examiner has not relied upon prior art in rejecting the claims on appeal. Rather, claims 5 through 9 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Claims 5, 9 and 11 through 18 also stand rejected under 35 U.S.C. § 112, first paragraph (enablement). We reverse. In addition, we raise an issue for the examiner and appellants to consider upon return of the application.

DISCUSSION

1. Definiteness

As set forth on pages 2-3 of the Examiner's Answer, the examiner considers claims 5 to 9 to be indefinite through their use of the word “homology” since “this term is

recognized to evolutionary origins by practitioners of this art and it would seem that that definition is not what is intended here."

Manifestly, the examiner has not used the correct legal standard in determining whether claims 5 through 9 comply with the definiteness requirement of 35 U.S.C. § 112, second paragraph. As set forth in In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971), this section of the statute only requires that the claims "set out and circumscribe a particular area with a reasonable degree of precision and particularity." The court stated that claim language must be analyzed "not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary skill in the pertinent art." Here, all we have is the examiner's unsupported conclusion that the word "homology" has been somehow misused by appellants. The examiner has not provided any analysis based upon prior art usage of this word or how the supporting specification of the application uses this word in support of this position. Absent a fact based explanation from the examiner premised upon the correct legal standard, the rejection can not be sustained.

The examiner has also rejected claims 5 through 9 under this section of the statute on pages 7-8 of the Examiner's Answer. The examiner questions whether the reference to "the sequence shown in Figure 1" in claims 5 and 6 refers to the amino acid sequence or the nucleotide sequence depicted in this figure. As explained by appellants, it is quite

clear that claim 5 refers to the amino acid sequence of Figure 1 while claim 6 refers to the nucleotide sequence of Figure 1.

Both rejections under 35 U.S.C. § 112, second paragraph, are reversed.

2. Enablement

As explained on pages 3-4 of the Examiner's Answer, the examiner believes that the claims on appeal must be limited to the “nucleic acid sequence of Figure 1.” We disagree.

Again, in making this rejection, the examiner has not used the correct legal standard. The issue raised by the examiner is whether one skilled in the art could make and use the claimed invention throughout its scope without undue experimentation. As set forth in the sentence bridging pages 3-4 of the Examiner's Answer:

> “It would require undue experimentation for one of skill in the art to have to make every protein which has 'at least 80% homology' with the protein whose sequence is given in Figure 1 and then to test every single one of these homologues to determine whether it will function to 'fold [newly synthesized proteins] into their biologically active conformation.”

As explained in PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 USPQ2d 1618, 1623 (Fed. Cir. 1996):

> In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim. See, e.g., In re Goodman, 11 F.3d 1046, 1050-52, 29 USPQ2d 2010, 2013-15 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212-14, 18 USPQ2d 1016, 1026-28 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991); In re Vaeck, 947 F.2d at 496, 20 USPQ2d at

> 1445. Enablement is lacking in those cases, the court has explained, because the undescribed embodiments cannot be made based on the disclosure in the specification, without undue experimentation. But the question of undue experimentation is a matter of degree. The fact that some experimentation is necessary does not preclude enablement; what is required is that the amount of experimentation "must not be unduly extensive." Atlas Powder Co., v. E.I. DuPont de Nemours & Co., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984). The Patent and Trademark Office Board of Appeal summarized the point well when it stated:
>
> > The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.
>
> Ex parte Jackson, 217 USPQ 804, 807 (1982).

Here, all the examiner has established is that some experimentation would be required to make and use other embodiments of the claimed invention. What the examiner has not done is perform the fact finding needed in order to reach a proper conclusion of undue experimentation. The examiner has not relied upon any evidence in support of this rejection which would establish that making and testing other sequences beyond those described in the present specification amounts to undue experimentation. The examiner's unsupported conclusion does not suffice.

The rejection under 35 U.S.C. § 112, first paragraph, is reversed.

OTHER ISSUES

The following statement appears at page 4 of the Examiner's Answer:

> It is also noted that the only DNA segments, vectors, and hosts for which the specification provides adequate written description are those limited to the DNA sequence of Figure 1.

While raising an issue under the written description requirement of 35 U.S.C. § 112, first paragraph, the examiner has not made a separate rejection under this section of the statute. Rather, the only rejection made is under the enablement requirement, not the written description requirement.

Subsequent to the briefing in this appeal, our appellate reviewing court issued the decision in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Therein, the court determined that claims to genetic material which are couched only in functional language describing what the DNA does do not distinguish the claimed genus from others and are not described in accordance with 35 U.S.C. § 112, first paragraph, by equally broad language in the application.

Upon return of the application, the examiner should review all of the claims pending in this application and determine whether they comply with the written description requirement 35 U.S.C. § 112, first paragraph. In so doing, the examiner should take into account the decision in University of California, supra. Also, the examiner should note that claims, such as claims 11 and 16, define genetic material in a manner which is broader than the definition of the genetic material in claim 5. It does not appear that the examiner has separately considered the patentability of claims 11 and 16 on this record.

The decision of the examiner is reversed.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)
	)
	)
	)
WILLIAM F. SMITH Administrative Patent Judge	) BOARD OF PATENT) APPEALS AND) INTERFERENCES
	)
	)
HUBERT C. LORIN Administrative Patent Judge	)

Patrea L. Pabst
Kilpatrick & Cody
1100 Peachtree St., Suite 2800
Atlanta, GA 30309-4530